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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/865,044	05/29/97	APPINO	P58317052

HM12/1101

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EXAMINER BAWA, R

ART UNIT 1619	PAPER NUMBER 20
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DATE MAILED: 11/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

08/865,044

Applicant(s)

Appino

Examiner

Bawa

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-17 and 23-28 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-17 and 23-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10-17 and 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCrea et al (U.S.P. 5,290,530).

McCrea et al disclose topical compositions that contain all four claimed ingredients (e.g., see abstract and claims). These compositions contain (1) a cosmetic or therapeutic agent (abstract, column 7-8); (2) the claimed linear volatile silicone, namely, hexamethyl disiloxane (col. 9, line 58, claim 10); (3) silica as the suspending agent (col. 10, abstract); and (4) other optional/conventional ingredients (column 15-16).

The claimed invention is directed towards a topical sprayable composition containing hexamethyl disiloxane, therapeutic/cosmetic agent, silica powder and conventional additives or

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fillers. Furthermore, this composition is contained in a conventional delivery device, absent evidence to the contrary. The method of spraying the topical compositions onto the skin is nominal and inherent to the claimed composition.

The cited analogous art lacks a specific disclosure of the amounts claimed. However, it would be prima facie obvious to one of ordinary skill in the art to optimize the amounts (% wt.) of the ingredients in view of the disclosure of McCrea et al and deliver it topically via conventional delivery devices. The motivation to optimize ingredients arises from the McCrea disclosure that shows such manipulation/optimization. Moreover, it is considered within the skill in the art to select optimal parameters of a composition, such as percents of components, in order to achieve a beneficial effect. [see *In re Boesch*, 205 USPQ 215 (CCPA 1980)]. Canisters of the type claimed are well known in the art to deliver topically-active compounds such as cosmetics or drugs. Note that the cited art is directed to the “topical delivery of a topically-active compound, either cosmetic or medicinal . . .” (Column 2, lines 19-20 of McCrea et al.). Additionally, such topical compositions are routinely packaged as pump-sprays (e.g., see column 1, lines 65-66 of McCrea et al.).

For the record, note the scope of the phrase “consisting essentially of” as follows:

Use of the phrase, “consisting essentially of” limits the scope of a claim to the specified ingredients and those that do not materially affect the basic and novel characteristics of a composition. [See *Ex parte Davis et al* 80 USPQ 488 (PTO Bd. APP, 1948); *In re Janakirama*, 317 F2d 952, 137 USPQ 893 (CCPA 1963); *In re Garnero*, 412 F2d 276, 162 USPQ 221 (CCPA

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1969)]. Applicant therefore has the burden of showing that the basic and novel characteristics of his composition would be materially changed if the unspecified ingredients not claimed were added. See *In re de Lajarate*, 337 F2d 870, 143 USPQ 256 (CCPA 1964)]. "Consisting essentially of" is a term open to the inclusion of all elements except for those which "deleteriously change" the basic and novel characteristics of the combination claimed.

The above-mentioned claims are directed towards a composition per se; its future intended use is not at issue from a patentability point of view. No criticality of the concentrations of the ingredients has been established. There is no comparative data of record in this case that (i) presents any unexpected results over the closest prior art; or (ii) establishes any improvements over the closest prior art.

The applicant's arguments concerning the presence of wax as an essential ingredient of McCrea have been considered. Note that there is no evidence or data of record to substantiate that an aerosol cannot be formulated in the presence of McCrea's wax. The opinion of the applicant regarding the "results which would likely be obtained" when operating within the scope of the claims does not present any additional objective evidence of non-obviousness. Hence it is entitled little weight. Note that: (i) the cited art is analogous because it pertains to the field of the inventor's endeavor and is also reasonably pertinent to the particular problem with which the inventor is concerned. [See *In re Oetiker*, 977 F.2d 1443, 24 U.S.P.Q. 2d 1443 (Fed. Cir. 1992)]; (ii) it is well established that the claims are given the broadest interpretation during examination; (iii) references are evaluated by what they suggest to one versed in the art, rather than by their

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specific disclosures. [See *In re Bozek*, 163 U.S.P.Q. 545 (CCPA 1969)]; and (iv) a conclusion of obviousness under 35 U.S.C. 103(a) does not require absolute predictability, only a reasonable expectation of success.

In light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been obvious within the meaning of 35 U.S.C. 103(a).

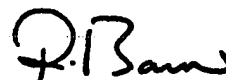
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mr. Raj Bawa whose telephone number is (703) 308-2423. The examiner can normally be reached on Tuesday-Friday from 7:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash, can be reached on (703) 308-2328. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Bawa



RAJ BAWA, Ph.D.
PRIMARY EXAMINER